

### REMARKS

Reconsideration of this application is respectfully requested.

#### Status of the Claims

Claims 1, 11, 18, 20, 31, and 36 have been amended to recite the chemical name for THIP and for clarification. Claims 14 and 34 have been amended to specify that the recited compound is obtained in a purity of more than 98% according to HPLC. This amendment is supported in the specification at, for example, page 11, lines 19-21. Claims 18 and 19 have been amended to delete "C<sub>1-12</sub> alkyl" from the definition of R'. Therefore, no new matter has been added to the application. Claims 1-37 are pending. Because claims 17 and 37 have been allowed, only claims 1-16 and 18-36 are at issue.

#### Allowable Subject Matter

Applicants gratefully acknowledge the allowance of claims 17 and 37.

#### Indefiniteness Rejections

Claims 1-15, 18, and 20-36 have been rejected under 35 U.S.C. § 112, second paragraph, as indefinite. The Examiner contends that the terms "THIP", "mild" (in the term "mild reducing agent"), and "≤" are unclear and that the phrases "high purity" and "according to HPLC" are confusing.

Claims 1, 18, 20, and 36 have been amended to replace the term "THIP" with its full chemical name, 4,5,6,7-tetrahydroisoxazolo[5,4-c]pyridin-3-ol. *See* page 1, lines 4-5 of the specification. Claims 11 and 31 have been amended to correct a typographical error in which "≤ 5" was printed as "≤."

The specification describes the term "mild reducing agent," stating that it is

a well-known expression to the skilled chemist, reference is made to Brown, H.C.; Krishnamurthy; *Tetrahedron*, 35, 1979, pp 567-607. Suitable examples are borohydrides.

(Page 4, lines 1-3, of the specification.) A copy of the Brown reference, titled "Forty Years of Hydride Reductions," is attached as Exhibit A. The usage of the term "mild reducing agent" in Brown demonstrates that "mild" pertains to the reducing power of the reagent, rather than temperature, and is the antithesis of "powerful." See Brown, page 571, last paragraph. Accordingly, the term "mild reducing agent" is well-known in the art and would not be the source of any confusion to the skilled artisan.

Claims 14 and 34 have been amended to specify that compound (8a) or (8b) was obtained at a purity of "more than 98% according to HPLC" as taught in the specification. See page 11, lines 19-21 of the specification. Accordingly, the rejection of the term "high purity" is moot.

The phrase "according to HPLC" specifies the standard for measuring the purity of the recited compound. The Examiner questions whether there is a difference between HPLC and other test methods, such as GC. However, specifying a test method does not render a claim indefinite, regardless of whether various test methods provide the same or different results. Indefiniteness exists when one of ordinary skill in the art would not understand the metes and bounds of the claim. See MPEP § 2173.02; *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379 (Fed. Cir. 2000). The skilled artisan is familiar with HPLC and would understand how to measure purity using this well-known method. Therefore, "according to HPLC" is definite.

For the above reasons, Applicants submit that the present rejections have been addressed and overcome. Withdrawal of this rejection is respectfully requested.

#### Enablement Rejections

Claims 1-16 and 20-35 have been rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. According to the Examiner, the specification does not enable the terms "leaving

group,” “mild reducing agent,” “nucleophile,” “alkylating agent,” and “dehydrating agent.” In each case, the Examiner contends that the specification is only enabling for some species and provides an example, stating that “it is not seen where this enables other [species].”

The test of enablement is whether the disclosure permits the skilled artisan to make and use the claimed invention without undue experimentation. MPEP § 2164.01. Factors to be considered include: (a) the breadth of the claims, (b) the nature of the invention, (c) the state of the prior art, (d) the level of one of ordinary skill, (e) the level of predictability in the art, (f) the amount of direction provided by the inventor, (g) the existence of working examples, and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988); MPEP § 2164.01(a).

“[T]he Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention.” *In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993). The Examiner’s analysis and conclusion “should focus on [the *Wands*] factors, reasons, and evidence that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement ... is not commensurate with the scope of protection sought by the claims.” MPEP § 2164.04 (emphasis in original).

Here, the Examiner fails to consider the *Wands* factors or provide any evidence or reason to doubt the enablement of the rejected claims. The Examiner merely makes conclusory statements that the terms are not enabled. Accordingly, the present rejection is improper.

Furthermore, the specification defines and provides suitable examples for each of these well-known terms (*see* page 3, line 24 to page 4, line 13), and one skilled in the art could readily select others. “The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art.” MPEP § 2164.03 (citing *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970)). Leaving groups, reducing agents, nucleophiles, alkylating agents, and dehydrating agents are well-known functional groups and reagents used routinely in organic chemistry. Given the wealth of knowledge in the art

regarding their use, the skilled artisan could easily practice the claimed invention using other, undisclosed species without undue experimentation.

The usage in the art of these terms in claims to chemical processes also demonstrates that they act in a predictable manner and do not involve undue experimentation. *See, e.g.*, U.S. Patent Nos. 7,230,111 and 7,223,767 ("leaving group"); 6,521,131 and 5,290,597 ("mild reducing agent"); 7,173,139 and 7,119,232 ("nucleophile"); 7,230,030 and 7,196,219 ("alkylating agent"); and 7,199,240 and 7,094,914 ("dehydrating agent").

Accordingly, the rejected claims are enabled with respect to these terms. For the above reasons, Applicants respectfully request that the present rejection be withdrawn.

#### Anticipation Rejections

Claims 18 and 19 have been rejected under 35 U.S.C. § 102(b) as anticipated by Krogsgaard-Larsen et al., *Acta Chemica Scandinavica B* 1977, 31:584-588. According to the Examiner, Krogsgaard-Larsen discloses in Scheme 2 a compound recited in claim 19 and the method recited in claim 18 of preparing THIP using the compound. Specifically, the Examiner refers to the following compound where n and m are 1.

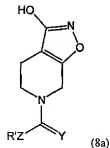


Claim 19 has also been rejected under 35 U.S.C. § 102(b) as anticipated by Perregaard et al. (U.S. Patent No. 4,353,910). According to the Examiner, the following compound disclosed in Perregaard anticipates claim 19.



(The applicants note that this compound has an oxo group on a ring atom, while compound (8a) has a hydroxyl group at the same position.)

Claims 18 and 19 have been amended to delete “C<sub>1-12</sub> alkyl” from the definition of R' in formula (8a).



Claims 18 and 19 now recite that R' is C<sub>2-12</sub> alkenyl, C<sub>3-8</sub> cycloalkyl, C<sub>3-8</sub> cycloalkenyl, acyl, or aryl optionally substituted with one or more C<sub>1-12</sub> alkyl, C<sub>1-12</sub> alkoxy, or aryl. Neither Krogsgaard-Larsen nor Perregaard teaches or suggests such a compound. Accordingly, claims 18 and 19 as amended are novel over Krogsgaard-Larsen and Perregaard. Withdrawal of the present rejections is respectfully requested.

CONCLUSION

In view of the above amendments and remarks, the applicants believe the pending application is in condition for allowance. If there are any remaining issues that the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

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